

BIOCOMPATIBLE WOUND DRESSING

This application claims the benefit under 35 U.S.C. § 119(e), of U.S. provisional patent application number 60/269,957 filed February 16, 2001.

5 **FIELD OF THE INVENTION**

This invention relates generally to wound dressings commonly associated with the vacuum induced healing of open wounds. More particularly, the present invention relates to a wound dressing, having a cell growth enhancing porous lattice, matrix, or scaffold, or a bioabsorbable layer as part of the dressing to enhance the wound healing.

10 **BACKGROUND OF THE INVENTION**

Vacuum induced healing of open wounds has recently been popularized by Kinetic Concepts, Inc. of San Antonio, Texas, by its commercially available V.A.C.[®] product line. The vacuum induced healing process has been described in commonly assigned U.S. patent 4,969,880 issued on November 13, 1990 to Zamierowski, as well as its continuations and
15 continuations in part, U.S. patent 5,100,396, issued on March 31 1992, U.S. patent 5,261,893, issued November 16, 1993, and U.S. patent 5,527,293, issued June 18, 1996, the disclosures of which are incorporated herein by this reference. Further improvements and modifications of the vacuum induced healing process are also described in U.S. patent 6,071,267, issued on June 6, 2000 to Zamierowski and U.S. patents 5,636,643 and 5,645,081 issued to Argenta et al. on June
20 10, 1997 and July 8, 1997 respectively, the disclosures of which are incorporated by reference as though fully set forth herein.

Substantial work has also been performed relating to the creation of bioabsorbable and includable, cell growth enhancing matrices, lattices, or scaffolds. Exemplary U.S. patents known

to applicant include Kemp et al. 5,256,418 issued October 26, 1993; Chatelier et al. 5,449,383 issued September 12, 1995; Bennett et al. 5,578,662 issued November 26, 1996; and two patents issued to Yasukawa et al. 5,629,186 issued May 13, 1997 and 5,780,281 issued July 14, 1998, both from a common parent application; the disclosures of which are incorporated by reference
5 herein.

As is well known to those of ordinary skill in the art, closure of surface wounds involves the inward migration of epithelial and subcutaneous tissue adjacent the wound. This migration is ordinarily assisted through the inflammatory process, whereby blood flow is increased and various functional cell types are activated. Through the inflammatory process, blood flow
10 through damaged or broken vessels is stopped by capillary level occlusion; thereafter, cleanup and rebuilding operations may begin. Unfortunately, this process is hampered when a wound is large or has become infected. In such wounds, a zone of stasis (i.e. an area in which localized swelling of tissue restricts the flow of blood to the tissues) forms near the surface of the wound.

Without sufficient blood flow, the epithelial and subcutaneous tissues surrounding the
15 wound not only receive diminished oxygen and nutrients, but also are also less able to successfully fight bacterial infection and thus are less able to naturally close the wound. Until the advent of vacuum induced therapy, such difficult wounds were addressed only through the use of sutures or staples. Although still widely practiced and often effective, such mechanical closure techniques suffer a major disadvantage in that they produce tension on the skin tissue
20 adjacent the wound. In particular, the tensile force required in order to achieve closure using sutures or staples may cause very high localized stresses at the suture or staple insertion point. These stresses commonly result in the rupture of the tissue at the insertion points, which can eventually cause wound dehiscence and additional tissue loss.

Additionally, some wounds harden and inflame to such a degree due to infection that closure by stapling or suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalization, with its attendant high cost, and major surgical procedures, such as grafts of surrounding tissues. Examples of wounds not readily treatable with staples or suturing include large, deep, open wounds; decubitus ulcers; ulcers resulting from chronic osteomyelitis; and partial thickness burns that subsequently develop into full thickness burns.

As a result of these and other shortcomings of mechanical closure devices, methods and apparatus for draining wounds by applying continuous negative pressures have been developed.

When applied over a sufficient area of the wound, such negative pressures have been found to promote the migration toward the wound of epithelial and subcutaneous tissues. In practice, the application to a wound of negative gauge pressure, commercialized by Assignee or its parent under the designation "Vacuum Assisted Closure" (or "V.A.C.[®]") therapy, typically involves the mechanical-like contraction of the wound with simultaneous removal of excess fluid. In this manner, V.A.C.[®] therapy augments the body's natural inflammatory process while alleviating many of the known intrinsic side effects, such as the production of edema caused by increased blood flow absent the necessary vascular structure for proper venous return.

While V.A.C.[®] therapy has been highly successful in the promotion of wound closure, healing many wounds previously thought largely untreatable, some difficulty remains. Because the very nature of V.A.C.[®] therapy dictates an atmospherically sealed wound site, the therapy must often be performed to the exclusion of other beneficial, and therefore desirable, wound treatment modalities. One of these hitherto excluded modalities is the encouragement of cell growth by the provision of an *in situ* cell growth-enhancing matrix.

Additional difficulty remains in the frequent changing of the wound dressing. As the wound closes, binding of cellular tissue to the wound dressing may occur. Use of traditional V.A.C.[®] therapy necessitates regular changing of the dressing. Reckless dressing changes can result in some tissue damage at the wound site if cellular tissue has grown excessively into the dressing.

Accordingly a primary object of the present invention is to provide an improved wound dressing for vacuum induced healing therapy, which overcomes the problems and limitations of the prior art.

A further object of the present invention is to provide a dressing that is also readily adaptable to a variety of wound sizes and shapes and that requires no inordinate modification of known procedures for administration of V.A.C.[®] therapy.

Another object is to provide a pad that enables the concurrent application of vacuum induced healing and cell growth enhancement in the treating of a wound by providing a bioabsorbable, or includable, porous cell growth enhancing matrix substrate thereupon.

An additional object of the present invention is to allow for controlled application of growth factors or other healing factors, which could be embedded in the dressing or introduced into the dressing through a port or other connector fitting.

Still another object of the present invention is to provide a fully and/or partially bioabsorbable wound dressing that minimizes disruption of the wound site during dressing changes.

A yet further object of the present invention is to provide such a dressing that is economical and disposable, but also safe for general patient use.

SUMMARY OF THE INVENTION

In accordance with the foregoing objects, the present invention generally comprises a foam pad for insertion substantially into the wound site and a wound drape for sealing enclosure of the foam pad at the wound site. The foam pad, comprised of a foam having relatively few open cells in contact with the areas upon which cell growth is to be encouraged so as to avoid unwanted adhesions, but having sufficiently numerous open cells so that drainage and V.A.C.[®] therapy may continue unimpaired, is placed in fluid communication with a vacuum source for promotion of fluid drainage, as known in the art. The foam pad is further comprised of a cell growth lattice, matrix, or scaffolding, all of which have been used in the art to describe similar constructs, is noninvasive to the known V.A.C.[®] therapy and requires no modification thereof. Additionally, or alternatively, the foam pad may be comprised of bioabsorbable polymers.

The foam pad of the present invention is provided with a bioabsorbable, or includable, fibrous growth-enhancing matrix. Numerous suitable materials for this purpose are known to the art, including collagen, dissolvable nylon, soluble plastics, and fibrous ceramic material. An exemplary fibrous ceramic material that may be utilized is an ultra-low density fused-fibrous ceramic manufactured by Materials Evolution and Development USA, Inc., under the trade name P.R.I.M.M.[™] (Polymeric Rigid Inorganic Matrix Material), and further described in U.S. Patent no. 5,951,295 issued on September 14, 1999 to Lyles, et al., which is incorporated herein by reference. Additional materials may include alginates, fibrin gels, fused fibers and other similar materials utilized by those skilled in the art, that are capable of providing an invadable space and scaffolding for cellular growth. Alternatively, the growth-enhancing matrix may be non-fibrous, such as a gel-like growth-enhancing matrix. This matrix comprises a cell growth enhancing substrate that is up to over 90% open space. The fibers, or other particles, and spaces create

nooks and crannies that provide an excellent environment to enhance cell growth, and thus further the process envisioned by the vacuum induced healing process.

Upon placement of the pad, having the cell growth enhancing substrate matrix embedded therein, an airtight seal is formed over the wound site to prevent vacuum leakage. In use the V.A.C.® therapy is conducted as known and, if desired, cell growth enhancement therapy is added by simply placing the matrix on the pad that is located within the wound. Given the addition of a suitable surface to which the fibrous lattice may be attached, the cell growth is channeled into the most desirable form and location, but is kept away from the pad itself. Utilization of bioabsorbable branched polymers in the pad itself, in addition to, or in place of the cell growth enhancing matrix, can allow the pad to remain in place during the healing process. As cell growth continues, the pad is absorbed, and there is no need to remove the pad.

An alternative embodiment comprises use of bioabsorbable branched polymers within a layer of the pad adjacent the wound, such that upon removal of the pad during dressing changes, the bioabsorbably branched polymer layer is left behind, leaving the wound site itself undisturbed. Additionally, the cell growth enhancing substrate matrix may be incorporated within the polymer layer to further enhance cellular growth at the wound site.

Accordingly, cell growth enhancement therapy may be conveniently combined with existing V.A.C.® therapies, without loss of V.A.C.® therapy performance and without inconvenience or overly increased cost.

Finally, many other features, objects and advantages of the present invention will be apparent to those of ordinary skill in the relevant arts, especially in light of the foregoing discussions and the following drawings and exemplary detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the invention will now be described with reference to the drawings of certain preferred embodiments, which are intended to illustrate and not to limit the invention, and wherein like reference numbers refer to like components, and in
5 which:

Figure 1 shows, in partially cut away perspective view, the preferred embodiment of the present invention as applied to a mammalian wound site.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Although those of ordinary skill in the art will readily recognize many alternative
10 embodiments, especially in light of the illustrations provided herein, this detailed description is exemplary of the preferred embodiment of the present invention, the scope of which is limited only by the claims that may be drawn hereto.

The present invention is a biocompatible wound dressing for use with negative pressure therapy. The term “wound” as used herein, may include burns, incisional wounds, excisional
15 wounds, ulcers, traumatic wounds, and chronic open wounds. As used herein, the term “pad” refers to foam, screens, other porous-like materials. The term “conventional pad” refers to polyurethane (PU) or polyvinylalcohol (PVA) foams commonly used with V.A.C.[®] therapy. The term “V.A.C.[®] therapy” as used herein, refers to negative pressure wound therapy as commercialized by the assignee or its parent, and further described in the aforementioned patents
20 and patent applications.

Referring now to the figures, the present invention 10 is shown to generally comprise a foam pad 11 for insertion substantially into the wound site 12 and a wound drape 13 for sealing enclosure of the foam pad 11 at the wound site 12. According to the invention, the foam pad 11

is modified to contain a cell growth-enhancing matrix, or lattice 14, whereby a desired highly porous cell growth enhancing substrate may be directed into and about the wound site 12. After insertion into the wound site 12 and sealing with the wound drape 13, the foam pad 11 is placed in fluid communication with a vacuum source for promotion of fluid drainage, as known to those of ordinary skill in the art. Foam pad 11 is modified from prior art pads in that the pad 11 comprises matrix 14 that is noninvasive to the known V.A.C.[®] therapy and therefore requires no modification thereof.

According to the preferred embodiment of the present invention, the foam pad 11, wound drape 13 and vacuum source are implemented as known in the prior art, with the exception of those modifications to the foam pad 11 detailed further herein. Each of these components is detailed in U.S. patent application Serial No. 08/951,832 filed October 16, 1997, which is a Continuation of U.S. patent application Serial No. 08/517,901 filed August 22, 1995, which is a Continuation-in-part of U.S. patent application Serial No. 08/293,854 filed August 22, 1994. By this reference, the full specification of U.S. patent application Serial No. 08/951,832 ("the '832 application"), including the claims and the drawings, is incorporated as though fully set forth herein.

As detailed in the '832 application, the foam pad 11 preferably comprises a highly reticulated, open-cell polyurethane or polyether foam for good permeability of wound fluids while under suction. As also detailed in the '832 application, the foam pad 11 is preferably placed in fluid communication, via a plastic or like material hose 15, with a vacuum source, which preferably comprises a canister safely placed under vacuum through fluid communication, via an interposed hydrophobic membrane filter, with a vacuum pump. Finally, the '832 application also details the wound drape 13, which preferably comprises an elastomeric material

at least peripherally covered with a pressure sensitive, acrylic adhesive for sealing application over the wound site 12.

According to the preferred method of the present invention, those components as are described in the '832 application are generally employed as known in the art with the exception
5 that the foam pad 11 is provided with a matrix 14. This matrix 14 is shown to comprise porous material 16 that has been formed into a plurality of sections 17. The material 16 is implanted in the foam pad 11 at the base 18 of the pad 11. Because it is necessary to trim the foam pad 11 in preparation for V.A.C.[®] therapy wound treatment, material 16 preferably is placed in the central portion of pad 11. Applicant does not intend to limit itself to a regular or symmetrical
10 arrangement of material 16 or sections 17 by use of the term "matrix".

Alternatively, or in addition to the preferred embodiment, the foam pad may be comprised of bioabsorbable branched polymers alone (not shown), or in combination with the matrix 14.

Upon placement of the pad 11, having the matrix 14 embedded therein, and/ or
15 protruding therefrom, and/or comprised of bioabsorbable branched polymers, the wound drape 13 is applied over the pad to form an airtight seal over the wound site. In use, the V.A.C.[®] therapy is conducted as known and, if desired, cell growth enhancement therapy is added by simply providing the matrix 14 comprising material 16. In this manner, cell growth enhancement therapy may be conveniently combined with existing V.A.C.[®] therapies, without
20 loss of V.A.C.[®] therapy performance and without inconvenience or overly increased cost.

EXAMPLE I

The above described open celled foam is formed into a pad. The general principles set forth in United States patent 5,795,584 issued to Totakura et al on August 18, 1998 at Col. 5

lines 5-42, are followed to create a structure superimposed on the bottom of the pad. Holes are placed in those portions of the non-bioabsorbable substrate relatively remote from the bioabsorbable cell growth enhancing matrix substrate. The matrix covers a portion of the pad located within the boundaries of the wound being treated. The pad is then completely covered by an airtight drape, and subjected to sub atmospheric pressure, as is the standard practice for utilizing V.A.C.® therapy. The matrix is absorbed within the expected useful life of the pad, so, that when the pad is removed, the matrix had been absorbed, and the growing cells are not disturbed. The pad is replaced, if necessary, either by a conventional pad or by a matrix containing pad, as deemed therapeutically necessary.

10 EXAMPLE II

A conventional pad is selected. A collagen cell growth matrix is applied to a portion of the bottom thereof. The general principles of V.A.C.® therapy are followed, with the matrix containing pad substituted for a conventional pad. During the expected duty cycle of the pad, the collagen matrix is absorbed by the growing cells, so that when the pad is removed, the matrix had been absorbed, and the growing cells are not disturbed. The pad is replaced, if necessary, either by a conventional pad or by a matrix containing pad, as deemed therapeutically necessary.

EXAMPLE III

The procedure set forth in EXAMPLE II is followed. However an ultra-low density fused-fibrous ceramic, sometimes referred to under the trademark P.R.I.M.M., is substituted for the collagen matrix thereof. The general principles of V.A.C.® therapy are followed, with the matrix containing pad substituted for a conventional pad. During the expected duty cycle of the pad, the collagen matrix is absorbed by the growing cells, so, that when the pad is removed, the matrix had been absorbed, and the growing cells were not disturbed. The pad is replaced, if

necessary, either by a conventional pad or by a matrix containing pad, as deemed therapeutically necessary.

EXAMPLE IV

Many suitable bioabsorbable materials have been used for sutures, surgical implements,
5 and the like. A small sample of these materials are set forth in the following U.S. patents, to wit:
5,997,568, issued to Lin on December 7, 1999 and the following patents issued in 1999 to Roby
et al: 5,914,387; 5,902,874 and 5,902,875. A selected one or more of these, or similar materials,
are placed upon a conventional pad. The general principles of V.A.C.[®] therapy are followed,
with the matrix containing pad substituted for a conventional pad. During the expected duty
10 cycle of the pad, the collagen matrix is absorbed by the growing cells, so, that when the pad is
removed, the matrix had been absorbed, and the growing cells were not disturbed. The pad is
replaced, if necessary, either by a conventional pad or by a matrix containing pad, as deemed
therapeutically necessary.

EXAMPLE V

15 A bioabsorbable branched polymer, similar to that described in U.S. patent 5,578,662
issued to Bennet et al., forms the pad. The general principles of V.A.C.[®] therapy are followed
with the bioabsorbable branched polymer pad substituted for the conventional pad. During the
expected duty cycle of the pad, the pad is absorbed by the growing cells, so that there is no need
to replace the pad and disturb the wound site. If further treatment is deemed necessary, a
20 conventional pad, or an additional matrix containing pad, or an additional bioabsorbable
branched polymer pad may be placed in the wound site, and V.A.C.[®] therapy continued.

While the foregoing description is exemplary of the preferred embodiment of the present
invention, those of ordinary skill in the relevant arts will recognize the many variations,

alterations, modifications, substitutions and the like are readily possible, especially in light of this description and the accompanying drawings. In any case, because the scope of the present invention is much broader than any particular embodiment, the foregoing detailed description should not be construed as a limitation of the scope of the present invention, which is limited
5 only by the claims that are drawn hereto.

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